

The Examiner stated that Sangekar discloses a formulation comprising a swellable polymer that may include HPMC, HPC, HMC, HEC and HPC which can be used alone or in combination, referencing column 2, lines 57-61. The Examiner also stated that Sangekar teaches the presence of a binder in the composition that may be ethylcellulose at column 3, lines 51-55, and inclusion of excipients and lubricants. The Examiner thus concluded that this reference teaches the combination of HPMC and HEC and further in combination with EC for the creation of a long acting pharmaceutical formulation.

It is respectfully submitted however that Sangekar does not provide the teachings asserted by the Examiner. More specifically, Sangekar is directed to a tablet composition of diltiazem comprising diltiazem and a swellable hydrophilic polymer. As taught specifically in column 2, lines 57-61, examples of the swellable hydrophilic polymers include:

“hydroxypropylmethyl cellulose; hydroxypropylcellulose; methylcellulose; hydroxymethylcellulose; hydroxyethylcellulose; hydroxypropylcellulose, which can be used alone or in combination; carboxymethyl cellulose and the sodium salt thereof, which can be used alone or in combination; and other hydrocolloids, such as acacia and guar gum. The preferred swellable hydrophilic polymer is either hydroxypropylmethylcellulose or hydroxypropylcellulose.”

Therefore, this passage does not teach combining any of the listed polymers. Instead, only the hydroxypropylcellulose (HPC) and the carboxymethyl cellulose (CMC) and the sodium salt thereof are taught for use with other polymers. Furthermore, Sangekar does not teach what combination would be made. Thus, the only two polymers that are taught that could be combined are HPC and CMC, which are not contemplated as the hydrophilic polymers as presently claimed in independent claims 1 or 30. This passage does not teach using a combination of polymer that would include for example HPMC, HEC and EC as presently claimed. Sangekar in fact teaches away from using a combination of polymers as presently claimed since the preferred swellable hydrophilic polymer is taught in column 2 to be either HPMC or HPC, and only HPC and CMC are taught as combinable. Moreover, while Sangekar further teaches the use of a binder that may comprise HPMC, HPC, CMC, EC and most preferred povidone, this teaching does not provide a suggestion for a combination with the polymers disclosed in column 2 to result in the composition presently claimed. Finally, examples 1-5 of Sangekar do not disclose a combination of any polymer other than HPMC and EC, which is not contemplated by the present claims. Thus, Sangekar does not teach or provide any guidance with respect to making any combination of polymers as presently claimed, and as such, cannot render the present claims obvious. Accordingly,

Sangekar certainly does not disclose or suggest to one of ordinary skill in the art the combination of HPMC and HEC and further EC.

Applicants previously provided detailed scientific showings in declaration form to establish that one cannot simply "mix and match" or "substitute" polymers since different dissolution profiles will result, whereby individual polymers are not interchangeable. The Examiner's attention is again directed to the showings in the Declaration which demonstrate the nonobviousness of the presently claimed compositions.

Stupak is relied upon for teaching of excipients. Stupak does not, however, suggest the combination of polymers as recited in the present independent claims. Therefore, the additional teachings of Stupak cannot in combination with Sangekar render obvious the invention as recited in the present claims. Furthermore, the combination of the teachings of these two references does not teach or suggest the unobvious advantages of the extended control release characteristic of the composition positively recited in the independent claims.

To reiterate, for obviousness to be determined, the (1) claimed invention must be considered as a whole; (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (4) reasonable expectation of success is the standard with which obviousness is determined.


Neither Sangekar nor Stupak suggest the combination of polymers claimed. Further, neither reference suggests any desirability of making the claimed combination or provides any guidance as to how to make such combination. The Examiner's attention is again drawn to the previously filed declaration which disclosed that different polymers are not readily interchangeable.

In view of the above submitted arguments, it is evident that the combination of the teachings of the references does not suggest to one skilled in the art that such specific elements of each reference may be combined to provide the presently claimed invention. Furthermore, there is no teachings in any of the cited references which would lead one skilled in the art to expect that any such combination of selected teachings would lead to a successful extended release formulation as presently claimed. For these reasons, the presently rejected claims cannot be considered to be obvious in view of the combined teachings of the cited art, whereby the rejection under 35 U.S.C. § 103(a) has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejection under 35 U.S.C. § 103(a) and places the present application in condition for allowance.

Reconsideration and an early allowance are requested.

Respectfully submitted,



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